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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,016	05/31/2005	Dong-Hyun Kim	7260P001	8746

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EXAMINER	
CLARK, AMY LYNN	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
12/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,016	KIM ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4 and 13-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on January 11, 2005 with the cancellation of Claims 1-3, and newly added Claims 4-6.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4 and 13-17 are under examination.

Claim Rejections - 35 USC § 103

Claims 1, 2, 4 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chin et al. (N*, JP 07-089863 A), in view of Ishida et al. (O*, JP 63-216432 A), Tsuji et al. (P*, JP 2001-112437 A), Shibata (U, "Chemistry and Cancer Preventing Activities of Ginseng Saponins and Some Related Triterpenoid Compounds," J. Korean Med. Sci. Vol 16 (Suppl) (2001) 28-37), Bae et al. (V*), Roberfroid (W*), Hikino et al. (Q*, JP 61-115013 A), Hashimoto et al. (R*, JP 03-277247 A), and http://web.archive.org/web/*/http://www.diabetic-lifestyle.com/articles/mar00_cooki_1.htm (X*). Newly applied as necessitated by amendment.

Chin teaches a method of making a food comprising ginseng inoculated with lactobacillus, which is a type of lactic acid bacteria, at a pH of 4.0 or higher (See page 4), wherein an extract of ginseng may be made from the stems of Siberian ginseng, roots of other ginsengs, such as Asian ginseng, American ginseng, or tissue cultures from Asian ginseng, American ginseng, Siberian ginseng, *Panax japonicas*, or *Panax*

notoginseng (See pages 4 and 5). Chin further teaches that the ginseng may be extracted with aqueous alcohol (which reads on organic) following shredding, crushing or grinding the ginseng, and subsequently drying the solution under vacuum to provide ginseng to a condition to add to the lactobacillus (See page 4). Chin further teaches that dried ginseng may be extracted with ethanol, which is an organic solvent (See page 13, Example 16). Chin further teaches that after fermentation with lactobacillus, a supernatant is obtained that contains ginenosides (which reads on saponins) and that the supernatant may be dried (See page 8) and that the supernatant may be subjected to chromatography to provide a purified saponin (See page 11).

Ishida teaches a method of making a yogurt containing medicinal ginseng wherein the ginseng (roots, natural products or tissue cultured products) is medicinal ginseng, such as *Panax ginseng*, *Panax japonicus* C. A. Meyer, *Panax quinquefollum* L., *Panax notoginseng* (Burk) F. H. Chen and *Eleutherococcus senticosus* (See pages 2 and 3) and wherein the yogurt is obtained by admixing lactic bacteria to cow milk or ewe milk, maintaining the temperature of the mixture at between 35 and 45 °C in an anaerobic condition, and fermenting the mixture for about 24 hours (See page 4). Ishida further teaches that the medicinal ginseng yogurt is made by combining the medicinal ginseng, which is made by mixing a dried article of medicinal ginseng or ginseng calluses in water for 24 hours, then combing the natural medicinal ginseng with water, mixing the mixture to provide a liquid, which was filtered, to obtain medicinal ginseng (See pages 6 and 7). Ishida further teaches that the medicinal ginseng is

inoculated with lactic acid bacteria and left to ferment for 25 hours at a temperature of 35 °C (See pages 7 and 8).

Tsuji teaches a method of making yogurt by combining milk with Bifidobacterium, such as *Bifidobacterium bifidum* and *Bifidobacterium infantis* (See page 3, paragraphs 0016-0018 and page 4, paragraph 0021) or *Lactobacillis*, which are both types of lactic acid bacteria, wherein the pH is generally between 4.0 and 7.0 and that the temperature at which the cultures are grown are at 30-39 °C (See page 2, paragraphs 0010). Tsuji further teaches that it is necessary to perform the process of making yogurt at a temperature of between 30 and 42 °C and by adding an acid (See page 2, paragraph 0014) to reduce the pH to 4-5.5 (See page 3, paragraph 0018, continued onto page 4).

Shibata discloses that ginsenosides are obtained by acid treatment using ginseng extracts (page 30, paragraph 1). Shibata further teaches that the ginsenosides were subjected to incubation with human intestinal flora, *Bifidobacterium and Fusobacterium* K-60 (See page 31, paragraphs 3 and 4).

Bae teaches that ginsenosides, which are extracted from ginseng, are added to Bifidobacterium K-506 and incubated (See columns 1 and 2, page 743). Bae further teaches that the incubation increases the pharmacologic activity of the compounds.

Roberfroid teaches that probiotics are viable microbial dietary supplement that beneficially affects the host through its effects in the intestinal tract and are widely used to prepare fermented dairy products such as yogurt or freeze-dried cultures. Roberfroid further teaches that the bacterial genera most often used as probiotics are lactobacilli and bifidobacteria and that after passage through the stomach and the small intestine,

some probiotics survive and become established transiently in the large bowel. Indeed, the colon's fermentation capacity may be modified after probiotic intake, and oral intake of certain lactic acid bacteria will increase the number of lactobacilli or bifidobacteria in human feces (See page S1682S).

Morishita teaches a method of extracting medicinal plants using methanol, aqueous ethanol or water, wherein the medicinal plants are roots, leaves, buds and fruit of ginseng, which may be purified and formulated into tables, granules and capsules of oral administration.

Hikino teaches a cosmetic containing a polysaccharide obtained from ginseng, which reads on an extract of ginseng, obtained *Panax ginseng*, *Panax japonicus* C. A. Meyer, *Panax quinquefollum* L. or *Panax notoginseng* having a skin-activating effect and suitable for promotion of beauty and health of the skin.

http://web.archive.org/web/*/http://www.diabetic-lifestyle.com/articles/mar00_cooki_1.htm teaches that yogurt may be used as a soothing ointment for sunburn, as a cosmetic mask and that yogurt is beneficial to the skin.

Chin does not teach that the composition is a pharmaceutical composition, nor does Chin teach treating ginseng with an acid solution. However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of preparing a pharmaceutical composition as taught by Chin to provide the instantly claimed invention because at the time the invention was made, a method of making a yogurt containing medicinal

ginseng was known in the art reciting the same incubation steps as Chin, as clearly taught by Ishida, as was using different types of lactic acid bacteria with a pH of between 4 and 7 and to maintain the pH, acid should be added to the composition, as clearly taught by Tsuji, as was that ginsenosides are obtained by acid treatment using ginseng extracts and that the ginsenosides were subjected to incubation with human intestinal flora, *Bifidobacterium and Fusobacterium* K-60, which are both types of lactic acid bacteria, as clearly taught by Shibata, as was ginsenosides, which are extracted from ginseng, are added to Bifidobacterium K-506 and incubated and that the incubation increases the pharmacologic activity of the compounds, as clearly taught by Bae, as was that probiotics are viable microbial dietary supplement that beneficially affects the host through its effects in the intestinal tract and are widely used to prepare fermented dairy products such as yogurt or freeze-dried cultures, that the bacterial genera most often used as probiotics are lactobacilli and bifidobacteria and that after passage through the stomach and the small intestine, some probiotics survive and become established transiently in the large bowel and that the colon's fermentation capacity may be modified after probiotic intake, and oral intake of certain lactic acid bacteria will increase the number of lactobacilli or bifidobacteria in human feces, as clearly taught by Roberfroid, as was a method of extracting medicinal plants using methanol, aqueous ethanol or water, wherein the medicinal plants are roots, leaves, buds and fruit of ginseng, which may be purified and formulated into tables, granules and capsules of oral administration, as clearly taught by that Morishita, as was that a cosmetic containing a polysaccharide obtained from ginseng, which reads on an extract

of ginseng, obtained *Panax ginseng*, *Panax japonicus* C. A. Meyer, *Panax quinquefollum* L. or *Panax notoginseng* has a skin-activating effect and suitable for promotion of beauty and health of the skin, as clearly taught by Hikino, as was that that yogurt may be used as a soothing ointment for sunburn, as a cosmetic mask and that yogurt is beneficial to the skin, http://web.archive.org/web/*/http://www.diabetic-lifestyle.com/articles/mar00_cooki_1.htm.

It would clearly have been obvious to one of ordinary skill in the art to use acid and heat-treatment for the extraction *of Panax ginseng* to obtain saponins, such as ginsenosides and to use the ginsenosides along with intestinal-bacteria such as *Bifidobacterium* and *Fusobacterium* K-60 to ferment, based upon the above teachings. Based on the reasonable expectation of success one of ordinary skill in the art would be motivated to use acid and heat-treatment for the extraction of ginsenosides because of the enhanced pharmacological components caused by heat-treatment as disclosed by and to ferment the compounds also based upon the above teachings..
Furthermore, one of ordinary skill in the art would have reasonable expectation of success in using such a composition for a skincare composition because the beneficial properties of the ingredients are taught by the cited references.

It is noted that the references do not teach that the composition can be used for treating or preventing human or mammal suffering from brain strokes or brain diseases, as is instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a

structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

Please also note that the order of the method steps do not matter provided that the final product as disclosed in the art is the same as that claimed by Applicant. (See MPEP § 2111.01(I)).

It has been held that combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, since each of the references teach that plant parts and extracts of ginseng and that yogurt, which can be made by using lactic acid

bacteria, such as *Bifidobacterium*, as effective ingredients in compositions for treating skin, it would have been obvious to combine these plants with the expectation that such a combination would be effective in pharmaceutical, such as pharmaceutical skin care compositions. Thus, combining them flows logically from their having been individually taught in prior art.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

In response to Applicants arguments that the Examiner fails to provide a reference to describe treating ginseng with an acid solution prior to subsequently fermenting the organic extract, as claimed, please note that the Applicant's arguments are moot since the originally filed claims did not recite the method steps as now claimed. Furthermore, it should be noted that the order of the method steps do not matter provided that the final product as disclosed in the art is the same as that claimed by Applicant. (See MPEP § 2111.01(I)). Finally, in response to Applicants argument that the specification discloses these newly added and amended method steps and provides examples with regards to these newly recited limitations, although the claims are interpreted in light of the specification, it should be noted that limitations from the

specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, the Examiner did not make the previous rejection upon the method steps Applicant disclosed in the specification but did not include in the claims.

Response to Arguments

Claim Rejections - 35 USC § 112

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 20 September 2007, with respect to the rejection of claims 1, 2 and 4 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement have been fully considered and are persuasive. The rejection of claims 1, 2 and 4 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has been withdrawn.

Claim Rejections - 35 USC § 103

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 20 September 2007, with respect to the rejection of claims 1, 2, 4, and 5 under 35 U.S.C. 103(a) as being unpatentable over Ishida et al. (O*, JP 63-216432 A, Translation provided herein), in view of Tsuji et al. (P*, JP 2001-112437 A, Translation provided herein), Bae et al. (V*), Roberfroid (W*), Chin et al. (N*, JP 07-089863 A, Partial translation provided herein), Hikino et al. (Q*, JP 61-115013 A, Partial translation provided herein), Hashimoto et al. (R*, JP 03-277247 A, Translation provided

herein) and http://web.archive.org/web/*/http://www.diabetic-lifestyle.com/articles/mar00_cooki_1.htm (X*) have been fully considered, however, are not found fully persuasive. However, based upon the newly recited method step, wherein Applicant claims, "extracting an organic extract from ginseng", the rejection is previously written is withdrawn. However, a new grounds of rejection is made under 35 U.S.C. 103(a) with regards to claims 1, 2, 4, 6, 26 and 27 as being unpatentable over Chin et al. (N*, JP 07-089863 A), in view of Ishida et al. (O*, JP 63-216432 A), Tsuji et al. (P*, JP 2001-112437 A), Shibata (U, "Chemistry and Cancer Preventing Activities of Ginseng Saponins and Some Related Triterpenoid Compounds," J. Korean Med. Sci. Vol 16 (Suppl) (2001) 28-37), Bae et al. (V*), Roberfroid (W*), Hikino et al. (Q*, JP 61-115013 A), Hashimoto et al. (R*, JP 03-277247 A), and http://web.archive.org/web/*/http://www.diabetic-lifestyle.com/articles/mar00_cooki_1.htm (X*).

Since the Examiner has reapplied the original references, the Examiner addresses Applicant's arguments above after the newly applied rejection.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
AU 1655

Amy L. Clark
December 6, 2007

TERRY MCKELVEY, PH.D.
SUPERVISORY PATENT EXAMINER